

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

To:

see form PCT/ISA/220

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/GB2005/000367

International filing date (day/month/year)
03.02.2005

Priority date (day/month/year)
03.02.2004

International Patent Classification (IPC) or both national classification and IPC
G01N33/543, A61B5/00

Applicant
SPHERE MEDICAL LTD

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
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Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

Box No. II Priority

1. ☒ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43bis.1 and 64.1) is the claimed priority date.
2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 25-27

because:

- ☒ the said international application, or the said claims Nos. 25-27 relate to the following subject matter which does not require an international preliminary examination (*specify*):

see separate sheet

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☐ no international search report has been established for the whole application or for said claims Nos.
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
 - the written form ☐ has not been furnished
 - ☐ does not comply with the standard
 - the computer readable form ☐ has not been furnished
 - ☐ does not comply with the standard
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
- ☐ See separate sheet for further details

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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	2-3,8-9,13,26
	No: Claims	1,4-7,10-12,14-25,27
Inventive step (IS)	Yes: Claims	
	No: Claims	1-27
Industrial applicability (IA)	Yes: Claims	1-24
	No: Claims	25-27

2. Citations and explanations

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rules 43bis.1 and 70.10)

and /or

2. Non-written disclosures (Rules 43bis.1 and 70.9)

see form 210

**WRITTEN OPINION OF THE
 INTERNATIONAL SEARCHING
 AUTHORITY (SEPARATE SHEET)**

International application No.

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item III

The scope of claims 25-27 encompasses embodiments related to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT (diagnostic methods to be carried out in vivo involving the treatment of the living human/animal body by surgery). Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Art. 34 (4) (a) (I) PCT).

item V

1.) Reference is made to the following documents:

- D1: WO-A-2004/027393
- D2: US-A-2003/0053935
- D3: US-A-5,910,286
- D4: B. Jakoby et al (1999) Sensors & Actuators 76, 93
- D5: WO-A-00/22425
- D6: US-B-6,197,503
- D7: WO-A-99/17107
- D8: M. C. Blanco-López (2004) Trends in Anal. Chem. 23, 36

2.) The subject-matter of claims 1, 4-7, 10-12, 14-25 and 27 is not novel within the sense of Art. 33 (2) PCT, for the following reasons:

D2 (see fig. 5) anticipates the subject-matter of claims 1, 4-5, 11-12, 14-16, 20-21, 23, 25 and 27 for analogous reasons as discussed below for D1 in item VI.

D3 (see figs. 2a, 5a, 6; col. 4, l. 27 to col. 6, l. 45) and D4 (figs. 1 & 3) disclose piezoelectric acoustic sensors comprising a planar piezoelectric substrate and a molecular imprinted polymer between emitter and receiver electrodes patterned on the planar substrate. For analogous reasons as discussed for D1-D2, it is considered that D3 anticipates the subject-matter of claims 1, 4-5, 11-12, 14-15, 18-23, 25 and 27 and D4 anticipates the subject-matter of claims 1, 4, 12, 20-21, 23, 25 and 27.

D5 (see figs. 1-3; p. 6-7) discloses a microsystem in which an array of microwells are formed on a silicon substrate coated with a metallic layer by deposition (and patterning) of a coating layer of polyimide (see p. 13, l. 4-24). The bottom of each well works as working electrode for deposition of a layer of electropolymerized polypyrrole (p. 14, l. 31 to p. 15, l. 17) having affinity binding moieties as pendant groups. D5 anticipates the subject-matter of claims 1, 4-7, 10, 16-18, 20-25 and 27.

D6 (see figs. 1 & 3) discloses an integrated optical biochip comprising cavities formed on a substrate, each cavity being coated with a sensitive layer, i. e. a molecular imprinted polymer (col. 6, l. 53-54). D6 anticipates the subject-matter of claims 1, 4, 20-23, 25 and 27.

3.) The subject-matter of dependent claims 2-3, 8-9, 13 and 26 is considered to be novel, but not inventive within the sense of Art. 33 (3) PCT because it relates to obvious alternatives of the sensor/method of claims 1/25, which fall within the routine practice in this technical field and which do not seem to result in any unexpected technical effect. The attention of the applicant is drawn in particular to D7 (see p. 3, l. 19-28), which discloses a biosensor having annular confinement structures filled with biorecognition molecules formed on a planar substrate. D8 has been cited as background.

item VI

D1 (intermediate document) will be considered for assessing novelty of the subject-matter claimed when the application enters the regional phase. This document (see fig. 5) discloses a resistive sensor comprising a substrate [200] with two electrochemical systems (a reference and a sample), each one formed by a couple of electrodes deposited and protruding from the substrate [91/93 and 101/103], each couple of electrodes working as a limiting structure that defines an interior space between both electrodes which is filled by a molecular imprinted polymer [92]. It would appear that D1 discloses the subject-matter of claims 1, 4-5, 11-12, 14-16, 20-21, 23, 25 and 27.